Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2006 list were published in the Federal Register in December 2006.

New Approvals

ANADA Number: 200-394

Pioneer Product:	103-037
Trade Name:	Gentamicin Piglet Injection
Ingredients:	Gentamicin sulfate
Sponsor:	Sparhawk Laboratories, Inc.
Approval Date:	November 17, 2006
Status:	OTC
Route:	Intramuscular
Species:	Swine, piglets only up to 3 days of age
Drug Form:	Sterile solution
Concentration:	5 mg/mL
Indications:	For the treatment of porcine colibacillosis caused by strains of *E. coli* sensitive to gentamicin.
Tolerance:	*21 CFR 556.300* - 0.1 part per million (ppm) in muscle, 0.3 ppm in liver, and 0.4 ppm in fat and kidney.
Withdrawal:	40 days

21CFR 522.1044

ANADA Number: 200-407

Pioneer Product:	046-109
Trade Name:	Lincomycin-Spectinomycin Water Soluble Powder
Ingredients:	Lincomycin hydrochloride/spectinomycin dihydrochloride pentahydrate
Sponsor:	Agri Laboratories, Ltd.
Approval Date:	November 9, 2006
Status:	OTC
Route:	Oral
Species:	Chickens
Drug Form:	Soluble powder
Concentration:	Each 75 gram pouch contains 16.7 grams lincomycin and 33.3 grams spectinomycin
Indications:	For use in chickens up to 7 days of age as an aid in the control of: Airsacculitis caused by either *Mycoplasma synoviae* or *Mycoplasma gallisepticum* susceptible to lincomycin-spectinomycin. Complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin
Tolerance:	*21 CFR 556.600* - Spectinomycin: 0.1 part per million in uncooked edible tissues. *21 CFR 556.360* - Lincomycin: not required
Withdrawal:	0 hours

21CFR 520.1265

ANADA Number: 200-445

Pioneer Product:	091-739
Trade Name:	Primex® Equine Liquid Wormer
Ingredients:	Pyrantel pamoate
Sponsor:	First Priority, Inc.
Approval Date:	November 3, 2006
Status:	OTC
Route:	Oral
Species:	Horses and ponies
Drug Form:	Suspension
Concentration:	50 mg/mL
Indications:	For the removal and control of mature infections of large strongyles (*Strongylus vulgaris, S. edentatus, S. equines*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*) and small strongyles in horses and ponies

21CFR 520.2043

NADA Number: 141-264

Trade Name:	Nuflor®
Ingredients:	Florfenicol
Sponsor:	Schering-Plough Animal Health Corp.
Approval Date:	November 3, 2006
Status:	VFD
Route:	Oral
Species:	Swine
Drug Form:	Type A Medicated Article
Concentration:	4% Florfenicol (40 g/kg or 18.2 g/lb)
Indications:	For the control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Streptococcus suis*, and *Bordetella bronchiseptica* in groups of swine in buildings experiencing an outbreak of SRD.
Tolerance:	*21 CFR 556.283* - 2.5 parts per million of parent florfenicol in liver.
Withdrawal:	13 days
Exclusivity:	3 years

21 CFR 558.261; 21CFR 558.4,

ANADA Number: 200-434

Pioneer Product:	122-272
Trade Name:	SMZ-Med™ 454 Soluble Powder
Ingredients:	Sodium sulfamethazine
Sponsor:	Cross Vetpharm Group, Ltd.
Approval Date:	November 3, 2006
Status:	OTC
Route:	Oral
Species:	Beef and nonlactating dairy cattle, swine, chickens and turkeys
Drug Form:	Soluble powder
Concentration:	Each package size contains 100% sodium sulfamethazine
Indications:	For treatment and control of disease caused by organisms sensitive to sulfamethazine: **Beef and nonlactating dairy cattle**: Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours)(*Escherichia coli*), necrotic pododermatitis (foot rot)(*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum),* acute metritis *(Streptococcus* spp.), and in beef cattle, acute mastitis (*Streptococcus* spp.). **Swine:** Treatment of porcine colibacillosis (bacterial scours) (*Escherichia coli*), and bacterial pneumonia (*Pasteurella* spp.). **Chickens:** Control of infectious coryza (*Haemophilus gallinarum*), coccidiosis (*Eimeria tenella, Eimeria necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella pullorum*). **Turkeys:** Control of coccidiosis (*Eimeria meleagrimitis*, *Eimeria adenoeides*).
Tolerance:	*21CFR 556.670* - 0.1 part per million in uncooked edible tissues of chickens, turkeys, cattle, and swine.
Withdrawal:	10 days for cattle, chickens, and turkeys 15 days for swine

21CFR 520.2261d

Actions Taken by FDA Center for Veterinary Medicine

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 012-491

Trade Name: Tylan® 40, Tylan® 100, and Tylan® 100 Cal
Ingredients: Tylosin phosphate
Sponsor: Elanco Animal Health
Approval Date: November 7, 2006
Exclusivity: 3 years

This application provides for use the addition of an alternative feeding regimen for the control of porcine proliferative enteropathies (PPE, ileitis) in swine: "feed 100 g tylosin per ton of completed feed for at least 3 weeks. Follow with 40 g tylosin per ton of complete feed until pigs reach market weight."

Additionally, provides for changes in the scientific nomenclature for *Brachyspira hyodysenteriae* as the organism associated with swine dysentery (formerly known as vibrionic swine dysentery) and for *Arcanobacterium pyogenes* (formerly *Actinomyces pyogenes*) as the organism associated with liver abscesses in cattle, and to reflect administrative revision of previously approved 'prevention" claims to "control" claims for the use of tylosin phosphate in swine for the control of swine dysentery and porcine proliferative enteropathies.

21CFR 558.625

ANADA Number: 200-247

Pioneer Product: 008-622
Trade Name: Oxytetracycline HCL
Ingredients: Oxytetracycline hydrochloride
Sponsor: IVX Animal Health, Inc.
Approval Date: November 9, 2006

This application provides adding a contraindication statement to the use directions for honey bees, updating the nomenclature or organisms listed in the honey bee indications to "For control of American foulbrood caused by *Paenibacillus larvae* and European foulbrood caused by S*treptococcus pluton* susceptible to oxytetracycline.", and other minor label changes.

21CFR 520.1660d

Trade Name Revisions

NADA Number: 141-193

Trade Name: Zubrin®
Ingredients: Tepoxalin
Sponsor: Schering-Plough Animal Health Corp.
Approval Date: December 14, 2006

This application provides for the trademark ™ to be changed to Registered trademark ®.

21CFR 520.2340

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 141-203

Trade Name: Deramaxx®
Ingredients: Deracoxib
Sponsor: Novartis Animal Health US, Inc.
Approval Date: December 15, 2006

This application provides for the trademark ™ to be changed to Registered trademark ®.

21CFR 558.538

Green Book Errata

NADA Number: 141-193

Patent Number: 4,826,868 Expiration Date: April 2, 2010

An incorrect expiration date was printed in the Dec. 2006 update to the Green Book.

NADA Number: 141-227

Exclusivity: 3 years

Supplemental approval for UlcerGard™, originally published in the November Green Book, failed to include notice of a three-year exclusivity. The three years of marketing exclusivity applies only to the new indication and an 8 day treatment duration for which this supplement was approved.

Notice(s)

The Food and Drug Administration (FDA) solicits comments regarding substances prohibited from use in animal food or feed; animal proteins prohibited in ruminant feed.

Submit written or electronic comments on the collection of information by February 2, 2007.

Submit electronic comments on the collection of information to: http://www.fda.gov/dockets/ecomments. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with docket number 2006N-0431.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

FR 70409-70410, December 4, 2006

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The Food and Drug Administration (FDA) is announcing a tentative schedule of forthcoming meetings of its public advisory committees for 2007.

CENTER FOR VETERINARY MEDICINE

Veterinary Medicine Advisory Committee	September 7, 2007
National Center for Toxicological Research (NCTR)	September day(s) to be announced

FOR FURTHER INFORMATION CONTACT: Theresa L. Green, Advisory Committee Oversight and Management Staff (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1220.

71 FR 78443-78445, December 29, 2006